

# CODEX ALIMENTARIUS COMMISSION



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Agenda Item 6

NFSDU/42 CRD 12

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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### GENERAL PRINCIPLES FOR THE ESTABLISHMENT OF NRVs-R FOR PERSONS AGED 6 – 36 MONTHS

#### UPDATED DRAFT GENERAL PRINCIPLES FOR ESTABLISHING NUTRIENT REFERENCE VALUES FOR PERSONS AGED 6 TO 36 MONTHS

*Prepared by the Chair (Ireland) and Co-Chairs (the United States of America and Costa Rica) of the EWG*

#### Purpose of this CRD

The purpose of this CRD is to provide updated draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months, following the feedback received on the Circular Letter ([CL 2021/56/OCS-NFSDU](#)) for this Agenda item (24 Codex Members (CMs), 1 Codex Member Organisation (CMO) and 3 Codex Observers (COs) provided feedback to the CL).

Based on this feedback, the EWG Chair and Co-Chairs describe the comments received on the draft General Principles presented in the Agenda Paper (CX/NFSDU 21/42/7) and make proposals to address these issues, as outlined below. In Appendix 1 of this CRD, draft additional text (to that presented in Annex in CXG 2-1985) required for General Principles for Establishing Nutrient Reference Values for Persons aged 6 to 36 months, is included.

#### Comments received on the draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months:

##### Preamble

Two CMs and 1 CMO are in favour of retaining the original text in the Annex in CXG 2-1985. This feedback is in favour of:

1. deleting the third point in the preamble on how the labelling information may be helpful to caregivers
2. including text on “how governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilisation, or requirements”.

One CMO was in favour of including the text on how “governments may also consider whether to establish separate food label values for specific segments of the age group 6 to 36 months”.

One CM noted that the scope of the Guidelines on Nutrition Labelling (CXG 2-1985) applies to nutrition labelling of all foods i.e., not just pre-packaged foods as indicated in the Preamble. However, another CM specifically supports the text indicating pre-packaged foods.

EWG Chairs and Co-Chairs propose:

1. The second sentence in the Preamble referring to the scope stops before “according to the Codex Guidelines CXG 2-1985 for pre-packaged foods”.
2. The third point indicating how this labelling information may be helpful should be deleted.  
~~3) These values may also be useful for setting nutrient levels for Codex Standards/Guidelines.~~
3. The original text in the Preamble of the Annex in CXG 2-1985 is retained as follows:

“In addition, governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements.”.

4. The Committee should consider whether the following statement: “Governments may also consider whether to establish separate food label reference values for specific segments of the age group 6 to 36 months” should be included.

### Definitions

Based on comments received about the terms **older infants** and **young child**, the EWG Chair and Co-Chairs propose the following:

1. to be more consistent with other Codex definitions for older infants and young children (including the most recently reviewed Codex Standard for Follow-up Formula)
  - a. the term **older infant** means a person from the age of 6 months and not more than 12 months of age (~~up to the first birthday~~)
  - b. the term **young child** means a person from the age of more than 12 months (~~starting 1 day after the first birthday~~) up to the age of three years (~~36 months, ending at the 3rd birthday~~)
2. these definitions should be removed from the General Principles and the Committee can give consideration to where these definitions would best be placed.

Based on the scientific report of derivation methods (available [here](#)) and the feedback from 1 CM and 1 CMO, the EWG Chair and Co-Chairs propose that the definition for Adequate Intake be re-worded as follows:

“The observed or experimentally derived intake by a defined population group that appears to sustain health (UNU/FAO/WHO/UNICEF (2007)).”

### Selection of suitable data sources to establish NRVs

Based on comments received, the EWG Chair and Co-Chairs propose that the original text in the Annex in CXG 2-1985 should be retained in the draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months where there is no need to accommodate changes for the population group aged 6 to 36 months.

Therefore, the original text in the Annex under 3.1 will be retained in the draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months.

### Appropriate Basis for Establishing NRVs - 3.2.1 Selection and priority of derivation methods for establishing NRVs-R

The feedback on approaches taken to derive Daily Intake Reference Values (DIRVs) from FAO/WHO and 6 RASBs was generally in support of the 3 category ranking proposed based on the comprehensive scientific report of derivation methods (available [here](#)).

The EWG Chair and Co-Chairs noted the issues raised and make the following specific proposals:

1. ***Issue raised:** More time will be required to consider all of the details outlined in the scientific report and how these relate to different nutrients.*

Proposal: When choosing the values for NRVs-R, each of the nutrients will be examined on a case-by-case basis, which will provide time to consider issues summarised in the scientific report relevant to each nutrient.
2. ***Issue raised:** Do the ranking of the methods need to be included in the Annex in CXG 2-1985 given the same scientific methods were used to consider the appropriate DIRV for the general population, but they are not listed in the General Principles for the general population.*

Proposal: The categorisation and ranking of the methods should be retained as drafted in the General Principles for establishing nutrient reference values for persons aged 6 to 36 months. Due to the much more limited scientific evidence available, more diversity is evident in approaches used to establish DIRVs for persons aged 6 to 36 months. This necessitates more detailed categorisation and ranking of derivation methods as described in the scientific report and summarised in the Draft General Principles.
3. ***Issue raised:** How will the WHO review of nutrient requirements for this age group impact on establishing NRVs-R by CCNFSDU.*

Proposal: The eWG Chair and Co-Chairs will take care to liaise closely with the WHO/FAO to avoid duplication of effort in establishing the NRVs-R values for persons aged 6 to 36 months in Codex.
4. ***Issue raised:** For many nutrients, NRVs-R for persons aged 6 to 36 months will be extrapolated down from older age groups. This indicates that having consistency with the values chosen as*

*NRV-R for the general population may be an important factor influencing the most appropriate NRVs-R for this younger age group.*

Proposal: the EWG Chair and Co-Chairs agree that the NRVs-R for the general population will be relevant in decisions on the most appropriate NRVs-R for persons aged 6 to 36 months (e.g. ensuring the values reflect relative differences in requirements). However, the scientific basis is of critical importance in determining the actual values. The scientific report provides a ranking for the various candidate values in terms of scientific rigour and, in addition, also indicates which values are from the same source as used for the NRVs-R for the general population (FAO/WHO and 6 RASBs). This will allow ease of assessment of both consistency with the values for the general population and the scientific rigour.

*Appropriate Basis for Establishing NRVs - 3.2.1.2 NRVs-R for both older infants and young children combined*

The EWG Chair and Co-Chairs considered feedback on this issue while noting the agreement reached at CCNFSDU40<sup>1</sup>, and propose the following:

1. remove any reference to the combined set of NRVs-R for older infants and young children from the General Principles
2. when the list of NRVs-R for persons aged 6 to 36 months is established, any reference necessary to a combined set can appear under the new addition to section 3 outlining the NRVs-R for persons aged 6 to 36 months.

*Structure of the General Principles for establishing nutrient reference values for persons aged 6 to 36 months*

Several delegations have expressed their preference for the draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months to be included as a separate Annex to CXG 2-1985. Others have underlined that the matter is interrelated, which should be reflected by integrating the draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months into Annex I of CXG 2-1985. To accommodate the wishes of both parties and to account for the proposal to include the draft Guidelines for Front of Pack Nutrition Labelling (FOPNL) as Annex II to the Guidelines on Nutrition Labelling (CXG 2-1985) as agreed by CCFL46 (REP 21/FL, Appendix IV), the Chairs of the eWG recommend that CCNFSDU considers that Annex I be amended to contain two parts, i.e. Part A (General principles for establishing nutrient reference values for the general population) and Part B (draft General Principles for establishing nutrient reference values for persons aged 6 to 36 months). The EWG Chair and Co-Chairs consider that this procedure is associated with only very minor amendment to the agreed text on General principles for establishing nutrient reference values for the general population (i.e., only adding the heading "Part A" before the preamble).

**Comments received on other areas:**

*Inclusion of sodium in the list of nutrients for the establishments of NRVs and the type of NRV for sodium*

- The majority (23 CMs, 3 COs) agree with the inclusion of sodium in the list of nutrients for the establishment of NRVs.
  - Eight CMs and 1 CO support the establishment of an NRV-NCD for sodium, while a further eight CMs and 1 CO want an NRV-R for sodium.
  - Six CMs and one CO while in favour of establishing an NRV for sodium, do not specify whether this should be an NRV-R or NRV-NCD.
- One CMO was not in favour as sodium was not among the agreed list of nutrients for establishing an NRV. Furthermore, establishing NRVs-NCD was not agreed.
- One CM was not in favour and suggested further work was needed to determine if sodium should be included in the list. If included, this CM indicated sodium should have an NRV-NCD established.
- There were concerns raised on whether the evidence base is sufficient for establishing NRVs-NCD for this age group. These concerns were expressed by both those who agreed and disagreed that an NRV should be established for sodium.

EWG Chair and Co-Chairs propose:

1. given the concerns about the lack of sufficient evidence for establishing NRVs-NCD for this age group, only NRVs-R should be established for the nutrients considered. When more evidence becomes

<sup>1</sup> that work would proceed to prepare two separate sets of NRVs-R (one for older infants and one for young children) and the decision on whether or not to combine the two sets would be deferred until the actual values in these two sets are established (para 116, REP19/NFSDU).

available to clarify the importance of NRVs-NCD for this young age group, the General Principles for establishing nutrient reference values for persons aged 6 to 36 months may require future amendments.

2. further discussion at CCNFSDU42 is required to determine if an NRV-R for sodium should be included in the list of nutrients for NRVs-R for persons aged 6 to 36 months.

*The type of NRV for potassium (NRV-R or NRV-NCD)*

The majority (10 CMs, 2 COs and 1 CMO) are in favour of establishing an NRV-R for potassium. A minority (4 CMs) are in favour of establishing an NRV-NCD for potassium.

EWG Chair and Co-Chairs propose that an NRV-R be established for potassium.

*CCFL*

The EWG Chair and Co-Chairs note that CCFL47 will not take place until 2023. As in the outstanding work for this project further issues may come up that might require to be addressed by CCFL as well, it is proposed that the Committee discusses at a later point in time a possible request to CCFL.

*Guidelines on Formulated Complementary Foods*

Based on feedback received, the EWG Chair and Co-Chairs propose that consideration of whether NRVs-R for persons aged 6 to 36 months established for labelling should also apply as reference criteria for vitamin and mineral composition in the Guidelines on Formulated Complementary Foods (CXG 8-1991), should be postponed until the actual values for NRVs-R have been established.

Appendix I**Draft Additional Text Required<sup>2</sup> for General Principles for Establishing Nutrient Reference Values for Persons aged 6 to 36 months****Part B****1. PREAMBLE**

These Principles apply to the establishment of Codex Nutrient Reference Values (NRVs) for persons aged 6 to 36 months. These values are used for nutrient declaration in labelling, ~~according to Codex Guidelines CXG 2-1985 for pre-packaged foods.~~ This labelling information may be helpful to caregivers of these individuals to:

- 1) estimate the relative contribution of individual products to overall healthful dietary intake of nutrients, and
- 2) compare the nutrient content between products.
- ~~3) These values may also be useful for setting nutrient levels for Codex Standards/Guidelines.~~

Governments are encouraged to use the NRVs, or alternatively, consider the suitability of the General Principles below including the level of evidence required, and additional factors specific to a country or region in establishing their own reference values for labelling purposes. In addition, governments may establish reference values for food labelling that take into account country or region specific factors that affect nutrient absorption, utilization, or requirements. [Governments may also consider whether to establish separate food label reference values for specific segments of the age group 6 to 36 months].

**2. DEFINITIONS**

In addition to relevant definitions under section 2 Definitions in Part A General Principles for Establishing NRVs-R for the General Population, the following definition is relevant to the setting of NRVs for persons aged 6 to 36 months:

- ~~a) The term **older infant** means a person from the age of 6 months and not more than 12 months of age (up to the first birthday).~~

~~The term **young child** means a person from the age of more than 12 months (starting 1 day after the first birthday) up to the age of three years (36 months, ending at the 3rd birthday).~~

- a) **Adequate Intake (AI)** is [*“The observed or experimentally derived intake by a defined population group that appears to sustain health (UNU/FAO/WHO/UNICEF (2007)).”*] ~~“The Adequate Intake is the recommended average daily intake level based on observed or experimentally determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate [used when an RDA INL98 cannot be determined].” This concept can also be referred to as Net Requirement, Estimated Values or Suggested Daily Intake.~~

**3. GENERAL PRINCIPLES FOR ESTABLISHING NRVs-R**

~~These principles are aligned with section 3 Annex: General Principles for Establishing NRVs for the General Population of these Guidelines, except that sections 3.1 – 3.4 will be modified to reflect the evidence base for nutrient needs of persons aged 6 to 36 months.~~

**3.1 Selection of suitable data sources to establish NRVs-R**

Relevant ~~and recent~~ daily nutrient intake [reference] values provided by FAO/WHO that are based on a [recent] review of the science should be taken into consideration as ~~one of the~~ primary sources in establishing NRVs.

Relevant ~~and recent~~ daily intake reference values (~~DIRVs~~) that reflect [recent] independent review of the science, from recognized authoritative scientific bodies (~~RASBs~~) ~~other than FAO/WHO~~ could also be taken into consideration. Higher priority should be given to values in which the evidence has been evaluated through a systematic review.

The daily intake reference values (~~DIRVs~~) should reflect intake recommendations for older infants and/or young children.

<sup>2</sup> to that presented in Annex in CXG 2-1985

## 3.2 Appropriate Basis for Establishing NRVs-R

### 3.2.1 Selection and Priority of Derivation Methods for Establishing NRVs-R

The NRVs-R should be based on daily intake reference values derived using the most rigorous scientific methods also considering data quality and strength of evidence. The methods used to derive daily intake reference values, ranked in order of overall scientific rigor, are:

Rank	Derivation Method	Description
1	Using physiological evidence for the target age group	The factorial summation of the nutrient requirements to support physiological growth or to maintain adequate stores. Includes nutrient requirements to maintain healthy plasma or urinary biomarkers, or to prevent deficiency disease.
2	Extrapolating up or down from DIRVs* of other age groups	Allometric, isometric and linear scaling methods based on DIRVs of infants, children or adults to estimate Adequate Intake (AI).
3	Estimates of nutrient intake of the target group; or interpolation	Based on AI and interpolation of DIRVs from DIRVs of older infants or DIRVs of younger children set from intake data.

\* DIRVs, Daily Intake Reference Values

**3.2.1.1** The NRVs-R should be based on evidence derived using Rank 1, 2, or 3 methods, preferably in that order. The scientific rigor and derivation of these values should be reviewed on a case-by-case basis and should consider the derivation method, quality of the underlying evidence, overall strength of the evidence and the upper levels of intake.

~~**3.2.1.2** A combined set of NRVs-R for both older infants and young children combined may be required for use in labeling of products intended for both older infants and young children.~~

### 3.2.2 Selection and Priority of Derivation Methods for Establishing NRVs-NCD

~~In some cases, it may be more appropriate to set NRVs based on NCD endpoints, rather than requirements to address chronic disease risk factors that may be established early in life and are associated with long-term health.~~

~~The following criteria should be considered in the selection of nutrients for the establishment of NRVs-NCD:~~

- ~~• Relevant convincing<sup>3</sup>/ generally accepted<sup>4</sup> scientific evidence or the comparable level of evidence under the GRADE classification<sup>5</sup> for the relationship between a nutrient and non-communicable disease risk, including validated biomarkers for the disease risk, for at least one major segment of the population (e.g. adults).~~
- ~~• Public health importance of the nutrient-non-communicable disease risk relationship(s) among Codex member countries.~~

~~Relevant and peer-reviewed scientific evidence for quantitative reference values for daily intake should be available in order to determine an NRV-NCD that is applicable to persons 6 to 36 months. When such evidence is not available, extrapolation from NRV-NCDs from the general population could also be considered.~~

~~Daily intake reference values from FAO/WHO or recognized authoritative scientific bodies that may be considered for NRVs-NCD include values expressed in absolute amounts or as a percentage of energy intake.~~

~~For practical application in nutrition labelling, a single NRV-NCD for older infants and/or young children should be established for each nutrient that meets the principles and criteria in this Annex.~~

~~An NRV-NCD for older infants and/or young children should be determined from the daily intake reference value for these target age groups, or if given by sex, the mean of males and females.~~

<sup>3</sup>At the time these guiding principles were drafted, the definition and criteria for “convincing evidence” from the following FAO/WHO report were used: Diet, Nutrition and the Prevention of Chronic Diseases. WHO Technical Report Series 916. WHO, 2003.

<sup>4</sup>For these General Principles the terms convincing/generally accepted evidence are considered synonymous.

<sup>5</sup>WHO’s Guidelines Review Committee. WHO Handbook for guideline development. Geneva, World Health Organization (WHO), 2014 ([http://www.who.int/kms/handbook\\_2nd\\_ed.pdf](http://www.who.int/kms/handbook_2nd_ed.pdf))

~~Where a daily intake reference value is based on a percentage energy intake, the NRV-NCD should be expressed in grams or milligrams based on an appropriate reference energy intake [xxxx kilojoules/ xxx kilocalories]<sup>6</sup> for older infants and/or young children.~~

### **3.3 Consideration of Upper Levels of Intake**

The establishment of NRVs-R for persons aged 6 to 36 months should also take into account daily intake reference values for upper levels of intake (UL) established by FAO/WHO or other RASBs where applicable.

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<sup>6</sup>Numbers to be obtained from WHO/FAO scientific advice.